UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,279	06/20/2003	Rima Kaddurah-Daouk	AVZ-005CCPA2CN	6449

959 7590 03/13/2007

LAHIVE & COCKFIELD, LLP
ONE POST OFFICE SQUARE
BOSTON, MA 02109-2127

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,279	KADDURAH-DAOUK, RIMA	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation application of application serial No. 08/958,374.

1. Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 18, 2006.

2. Applicant's election without traverse of invention group I, drawn to method of treating obesity, and creatine as the elected species in the reply filed on December 18, 2006 is acknowledged.

3. Note, newly added claims 15-20 do not read on elected species, creatine. Also claims 15-20 also encompass subject matter not within the elected invention, which drawn to a method of treating patient with obesity (or weight gain), who may also suffer disorders such as hypertension, hyperlipidaemia, osteoporosis and osteoarthritis. Claims 15-20 are drawn broadly to treatment of hypertension, hyperlipidaemia, osteoporosis and osteoarthritis, encompassing those without obesity or weight gain, which are not within the elected invention

The claims have been examined insofar as they read on elected invention and species.

Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4-7 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-20 of U.S. Patent No. 5,998,457. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '457 are drawn to method regulating imbalance of body weight, particularly obesity, or treating weight gain related disorder by administering a creatine compound.

Claim Rejections 35 U.S.C. 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,4-7 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating obesity and/or its related disorders, does not reasonably provide enablement for preventing obesity and/or its related disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claimed method is for preventing preventing obesity and/or its related disorders, such as hypertension, hyperlipidaemia, osteoporosis and osteoarthritis. The factor to be considered have been

summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the art, the relative skill of those in the art, the predictability of the art and the breadth of the claims. In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). The specification nor the prior art of record provide any guidance, direction, or working examples for one of skill in the art to use the invention in expectation of administering a therapeutically effective amount of creatine for prevention obesity or its related disorders. Although one would like to prevent obesity, numerous factors are associated with causing obesity and its related disorders, such that the prior art and the instant specification fail to enable the prevention of obesity and related disorders, but do enable treatment supporting suppressing or reducing the body weight. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity, The court in In re Fisher, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statue. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology and patient populations as the many types and causes for obesity and related disorders, that art does have product available for treatment of patients presenting with obesity, but the art and the evidence presented in the instant application fails to establish support for prevention, particularly by merely administering a compound, as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections 35 U.S.C. 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1,4-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almada et al. (US Patent 5,627,172, and US 5,726,146, IDS), in view of Meisner (US Patent 4,647,453, IDS) and Ishikawa et al. (JP 07196485).

12. Almada ('172) teaches that creatine derivatives are known to be useful as hypolipidemic agents and are useful for treating hyperlipidaemia, a disorder associated with obesity. See the abstract, col. 2, and line 60 to column 3, line 35, and the claims. Almada ('146) suggest that

creatine is useful for regulate body weight, i.e., increase lean body mass and decrease fat mass. See, the abstract and the claims.

The primary references do not teach expressly the employment of creatine for the treatment of subject with obesity.

However, Meisner teaches that creatine is known to be useful for tissue degenerative disorder, such as osteoarthritis. See, particularly, the claims. Ishikawa et al. teaches that lipid metabolism improving agents are useful for treatment of obesity and hyperlipidaemia. Ishikawa et al. also teaches a composition comprising creatine as useful for treatment obesity. See, particularly, the abstract, paragraph 28.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ creatine for treatment of patients with obesity and hyperlipidaemia or its related disorders, because creatine is known as a hypolipidemic agent and is useful for treating obesity related disorders such as hyperlipidaemia and osteoarthritis. Further, creatine has been suggested to be useful for reducing body fat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617